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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,054	08/25/1999	DAVID A. EDWARDS	AIR-108PA	6042

21005 7590 11/14/2002
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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/383,054	EDWARDS ET AL.
	Examiner	Art Unit
	Amy E Pulliam	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 August 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 50-69, 91-108 and 128-131 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 50-69, 91-108 and 128-131 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>19</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Extension of Time, and Amendment C, both received by the Office August 13, 2002, as well as the Information Disclosure Statement, received October 25, 2002.

New Matter

The previously asserted new matter rejections have been withdrawn, due to applicant's cancellation of the contested phrases.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50-69, 91-108, and 128-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durrani *et al* (hereinafter Durrani). Durrani discloses a process to directly spray dry a drug/lipid powder composition comprising preparing an aqueous solution containing a drug and a lipid containing ethanol solution. The mixture is then spray dried to get particles (p 40, claim 1). Durrani further teach that the drug may be selected from a group which includes insulin, granulocyte colony stimulating factor, interferons, growth factors, calcitonin, and interleukins (p 40, claim 2), as well as peptide hormones, and lung surfactant proteins (p 10-11).

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Durrani further teaches that the lipid may be selected from the group consisting of phosphatidylglycerol, phosphatidylcholine, phosphatidylinositol, phosphatidylethanolamines, and phosphatidylserine (p 41, claim 4). Lastly, Durrani teach that the diameter of the resulting particles is between 0.1 and 20 microns (p 14, 130).

Durrani does not disclose the percent protein integrity of the tap density of the spray dried particles. However, based on the fact that Durrani discloses the same components for the spray dried particles, it is the position of the examiner that the protein integrity and tap density are inherent characteristics, and would be the same as those claimed by applicant, absent the presentation of some unusual and/ or unexpected results. Further, on page 8 of the specification, applicant states that spray dies particles which have decreased stability are those without a phospholipid or with just an aqueous solvent. Durrani teaches the inclusion of phospholipids and organic solvents in his particles, so therefore, his particles would have the same improved characteristics as claimed by applicant.

In addition, Durrani does not teach that the phospholipid be present at 10 weight percent. However, Durrani does not specify a specific amount of the ingredients. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10

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USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430

(CCPA 1977).

One of ordinary skill in the art would have been motivated to make a spray dried composition of a drug and a lipid based on the generic claim of Durrani. The expected result would be a stable spray dried powder formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments regarding the rejection under 35 U.S.C. 103(a) have been fully considered but are not found persuasive. Applicant first argues that Durrani is not concerned with the stability of any drug in resulting spray dried powder form, and further, that even if this were inferred, Durrani doesn't address the stability of a protein drug in a resulting spray dried powder. These arguments are not found persuasive. Applicant is claiming a method of producing particles. The limitations in the claim which are drawn to improved stability of a protein do not carry patentable weight, unless it can be shown that the method of Durrani would not result in improved stability. All that is necessary to render applicant's instant claims obvious is the same method of producing spray dried particles, and as stated above, Durrani suggests this method. Durrani teaches directly spray dryings a drug/ lipid powder composition comprising preparing an aqueous solution containing a drug and a lipid containing ethanol solution and spray drying this solution to get particles. This clearly suggests applicant's broad process claims.

Additionally, applicant argues that Durrani does not teach the use of a protein. The examiner points to applicant's specification, where it states that "the term bioactive agent

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includes peptides and proteins..." and "specific examples of preferred biologically active agents which can be employed in the method of the invention include but are not limited to:

insulin...granulocyte colony stimulating factors, growth hormones...calcitonin... interleukins."

As stated in the above rejection, each of these active agents is discussed in the Durrani reference as drugs to be used in the invention. Therefore, Durrani *et al.* teach the same process for making particles and the same drugs to be used in the invention.

Applicant additionally argues that Durrani is has no examples of particles containing proteins. However, a reference does not have to exemplify each and every embodiment in order to be suggestive of each embodiment. In other words, Durrani is suggestive of the drugs listed, regardless of their absence in the examples, because he clearly teaches that these drugs can be used in his invention.

Applicant also argues that applicant does not require that the compositions be "phosphate free". This is not persuasive, however, because applicant does not require that phosphate be present in their composition. Therefore, inherently, applicant's composition is phosphate free.

Many of applicant's arguments appear to be drawn to the fact that Durrani *et al.* do not specifically discuss protein stability. These arguments are not persuasive, because applicant is claiming a method of making particles, not a method of increasing protein stability. Applicant's instant method of making claims are broad, and Durrani *et al.* do teach this method. If there is something present in applicant's method which makes the proteins stable, and this is not present in Durrani, then this limitation should be inserted into the claim, and comparative data should be provided showing any unexpected results. However, as the claim stands now, it is only

necessary that Durrani *et al.* teach the broad process steps, in order to suggest the limitations of applicant's instant claims. For these reasons, the above rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
November 7, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
[Handwritten Signature]